

**REMARKS**

Claims 1-34 were pending in the application. Claims 1, 10, and 23-25 have been amended. Upon entry of these amendments, claims 1-34 will be pending and under active consideration. Claim 1 is independent.

Claims 1, 10, and 23-25 are amended herein. Amendments to Claims 1 and 23-25 are made in response to Examiner's recommendation to remove the phrases "up to" and "additionally up to." Claims 23 and 25 are further amended to correct an inadvertent typographical error. Claim 1 is further amended to add "1996" after the term "DIN EN ISO 527 -1 to -3"; support is found at page 15, line 26. Claim 10 is amended to add the term "megapascals" prior to the abbreviation "MPa" as suggested by the Examiner. Claim 14 is amended to provide clarity as requested by the Examiner. The amendments are supported fully by the claims and/or specification as originally filed and, thus, do not represent new subject matter.

Applicants respectfully request entry of the amendments and remarks made herein into the file history of the present invention. Reconsideration and withdrawal of the rejections set forth in the above-identified Office Action are respectfully requested.

**I. The Rejection Under 35 U.S.C. § 102(b) Should Be Withdrawn**

The Office Action, at pages 3-4, paragraph 7, rejects Claims 1-7, 14, and 20-33 as allegedly being anticipated by U.S. Patent No. 5,783,269 to Heilmann (hereinafter, "Heilmann") under 35 U.S.C. § 102(b). The Office Action alleges that Heilmann anticipates the above-mentioned claims of the present invention based on the alleged disclosure by Heilmann of structurally identical multilayer films (*i.e.*, multilayer films having similar design characteristics in terms of the arrangement, number, and composition of the layers) having identical mechanical properties. Applicants traverse respectfully.

As a threshold matter, Applicants submit respectfully that the Examiner, as noted in the Office Action at paragraph 14, has previously conceded that Applicants' arguments were persuasive in overcoming the prior 35 U.S.C. § 102(b) rejection of Claims 1-7, 14, and 20-33 as allegedly anticipated by Heilmann. Applicants submit respectfully that the same elements that were lacking in Heilmann previously are still lacking in Heilmann now. Hence, Heilmann cannot anticipate the rejected claims now, for the reasons of record. Nevertheless, Applicants respond to the present allegations as follows.

Applicants submit respectfully that the claims of the present invention, as amended, are not anticipated by Heilmann. Without acquiescing in the propriety of the arguments made in the Office Action with respect to the identity of structure of the multilayer films of Heilmann compared with those of the present invention (i.e., multilayer films having similar design characteristics in terms of the arrangement, number, and composition of the layers), Applicants asserts respectfully that the mechanical properties of the films according to Heilmann are not identical with those of the films of the present invention and, in fact, the mechanical properties of films of the present invention are vastly superior to those of Heilmann.

As the Examiner is no doubt well aware, "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Applicants submit respectfully that the claimed element of "no measurable yield" is set forth neither expressly nor inherently in Heilmann. While Heilmann discloses films that are resistant to breakage under a drop test, Heilmann does not recite films that have no measurable yield as claimed by Applicants. In fact, Applicants submit respectfully that Heilmann teaches films that *do* yield. For example, Heilmann, at column 8, lines 41-43, recites that the "film is slightly biaxially oriented during

the production process at a stretching ratio of: longitudinal stretching/transverse stretching = 2.3/1.4.” Applicants submit respectfully that the claims of the present invention, as amended, are quite explicit in requiring that films of the present invention have *no measurable yield*, whereas the films of the prior art, *e.g.*, Heilmann, do have a measurable yield.

Respectfully, Applicants draws the Examiner’s attention to Table 3, at pages 36 to 37 of the specification as filed, which recites a comparison of the results of traction-elongation tests (according to DIN ISO 527-1 to -3) made on films manufactured according to the specifications of the prior art (labeled “Comp. Ex.”), including Heilmann, with films made according to methods of the present invention (labeled “Example”). Applicants submit respectfully that the films according to the prior art indeed have measurable yield in this test, whereas films according to the present invention have no measurable yield. The only exception is comparative example 1 (Comp. Ex. 1). However, the film of comparative example 1 requires an outer layer made of a polyester (PET1) which is a serious drawback, as is discussed in the present application’s specification at page 2, and falls outside the scope of the present claims. Applicants submit respectfully that the present invention, for the first time, provides films consisting of 100% polyolefin materials, optionally with low amounts of rubber materials, that avoid the use of PVC and PET while retaining the advantageous mechanical properties of films of the prior art that include these materials.

The Office Action alleges in paragraph 8 that “with regard to the claimed aspect of the film ‘displaying no measurable yield following steam sterilization at 121 degrees Celsius using a water spraying process,’ the scope of the claims falls within the limitations of Heilman *et al.* as discussed above. The method of obtaining the yield (product-by-process) is given little patentable weight.” Applicants submit respectfully that an incorrect standard is being applied to the rejected claims because the steam sterilization to which the claims refer is not a process for producing the films of the presently claimed invention. Rather, it is a

treatment to which films, particularly those in the medical products industry, are subjected in actual practice and which often causes weakening of films that results in film yield. It is one of the novel aspects of films of the present invention that they do not yield, even after being exposed to high temperature sterilization.

Applicants submit respectfully that it appears that the Office Action mistakes the meaning of the term “yield” as used in the rejected claims. In the context of the present claims, “yield” means the increase in elongation without additional stress exhibited by the films when undergoing a traction-elongation test according to DIN-ISO standards; see the specification at page 15, lines 12-26. The Office Action appears to misconstrue the term “yield” as referring to the output or outcome of a process; for example, the yield of product from a chemical reaction. Hence, there is no product-by-process at issue in the present claims, and Applicants submit respectfully that the Office Action thus errs in granting the claimed limitation of “no measurable yield” little weight on the basis of product-by-process theory. “No measurable yield” is indeed a claimed element of the present invention, and Heilmann does not teach or suggest this element. Accordingly, Applicants submit respectfully that Heilmann does not anticipate the claims of the present invention.

In view of the above, Applicants requests respectfully that the rejection of Claims 1-7, 14, and 20-33 under 35 U.S.C. § 102(b) be withdrawn.

## **II. The Rejections Under 35 U.S.C. § 103(a) Should Be Withdrawn**

### **A. Rejections over Heilmann**

The Office Action, at pages 5-6, paragraphs 10-11, rejects Claims 8-9, 18-19, and 20-22 as allegedly being obvious over Heilmann, under 35 U.S.C. § 103(a). The Office Action alleges that one of ordinary skill in the art would be able to readily determine

appropriate ranges of thickness, melting points, and VICAT temperatures to reach a desired end use through routine optimization. Applicants traverse respectfully.

As a threshold issue, Applicants submit respectfully that since, as noted above, Heilmann fails to teach, suggest, or disclose a multilayer film having no measurable yield, it is impermissible to consider obviousness of obtaining appropriate ranges of thickness, melting points, and VICAT temperatures to reach a desired end use through routine optimization.

Further, Applicants submit respectfully that Heilmann teaches away from determination of appropriate ranges by routine optimization. At column 6, lines 33-45, Heilmann discusses the complexities of manufacturing complex multilayer films. In particular, Applicants respectfully draw Examiner's attention to lines 34-37, in which Heilmann recites, "it was not predictable on the basis of past experience that such a complex multi-layer film of the type according to the invention could straightforwardly be achieved with success. Heilmann recites that success in this field is "surprising" and that "practical experience has repeatedly shown that, even with the assistance of sometimes tabulated polymer properties, such as composite adhesion data, the use of such materials does not lead to success." Finally, at column 6, lines 42-45, Heilmann recites that, "in other words, solving a particular problem in a multi-layer co-extruded film by simply making a selection from known materials is not in principle straightforwardly possible."

Applicants submit respectfully that it is well known in patent law that no finding of obviousness may be made over a reference that teaches away from construction of the present invention. In an obviousness inquiry, the relevant question is whether the prior art suggests the invention and whether the prior art provides one of ordinary skill in the art with a reasonable expectation of success. *In re O'Farrell*, 853 F.2d 894, 903, 7 USPQ2d 1673 (Fed. Cir. 1988). Both the suggestion and the reasonable expectation of success must be founded in

the prior art and not in the Applicants's disclosure. *In re Vacek*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991) (emphasis added). Applicants submit respectfully that the claimed invention is not obvious over Heilmann, because Heilmann does not teach, suggest or provide the requisite expectation of success for determination of appropriate ranges of thickness, melting points, and VICAT temperatures to reach a desired end use through routine optimization. In fact, as noted above, Applicants submit respectfully that Heilmann actually teaches away from such routine optimization. Accordingly, Applicants requests respectfully that the rejections of Claims 8-9, 18-19, and 20-22 under 35 U.S.C. § 103(a) be withdrawn.

**B. Rejections Over Heilmann In Light Of U.S. Patent No. 5,686,527 To Laurin *et al.* And U.S. Patent No. 6,348,568 To Barney *et al.***

The Office Action, at page 7, paragraph 12, rejects Claims 10-13, and 15-17 as allegedly being obvious over Heilmann in light of U.S. Patent No. 5,686,527 to Laurin *et al.* (hereinafter, "Laurin"), under 35 U.S.C. § 103(a). The Office Action alleges that Laurin cures a deficiency in Heilmann wherein Heilmann does not disclose films having a modulus of elasticity of less than 100 MPa for an inner layer and at least 400 MPa for an outer layer, as recited in the present claims. While admitting that Laurin does not disclose films having the recited moduli of elasticity (*i.e.*, Laurin discloses films having a modulus of elasticity in the range of 150-300 MPa), the Office Action alleges further that it would be obvious to one skilled in the art to vary the modulus of elasticity through routine optimization to obtain a desired result. At page 8, paragraph 13, the Office Action rejects Claim 34 of the present invention under 35 U.S.C. § 103(a) as allegedly being obvious over Heilmann in light of U.S. Patent No. 6,348,568 to Barney *et al.* (hereinafter, "Barney"). The Office Action alleges that Barney cures a deficiency in Heilmann whereby Heilmann fails to disclose packaging which stores fluid lipophilic emulsions. Applicants traverse respectfully.

As a threshold issue, Applicants submit respectfully that since, as noted above, Heilmann fails to teach, suggest, or disclose a multilayer film having no measurable yield and, since the Office Action does not assert that Laurin or Barney cures this deficiency, it is impermissible to consider obviousness of varying the modulus of elasticity through routine optimization to obtain a desired result or to consider packaging which stores fluid lipophilic emulsions.

Further, Applicants submit respectfully that Heilmann, either alone or in combination with Laurin or Barney, fails to show the necessary teaching, suggestion, or motivation, required to prove a *prima facie* case of obviousness. “It is impermissible to reconstruct the claimed invention from selected pieces of prior art absent some suggestion, teaching, or motivation in the prior art to do so.” *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1051-2, 5 USPQ2d 1434, 1438 (Fed. Cir. 1988). Absent some teaching, suggestion, or motivation found within Heilmann, Laurin, or Barney that the modulus of elasticity and/or storage of lipophilic solutions claimed by Applicants are desirable, it cannot be inferred that Applicants’s invention would have been obvious to one of ordinary skill in the art. “It is insufficient to select from the prior art the separate components of the inventor’s combination, using the blueprint supplied by the inventor.” *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143, 227 USPQ2d 543, 551 (Fed. Cir. 1985).

Applicants submit respectfully that Heilmann does not teach, suggest, or motivate one skilled in the art to combine the teachings of Laurin or Barney with Heilmann in order to reach the present invention. Moreover, in the case of Laurin, Applicants submit respectfully that Heilmann actually teaches away from the likelihood of achieving success through routine optimization. In light of these facts and the case law noted above, Applicants submit respectfully that the Office Action has failed to meet the burden necessary for combining Laurin and Barney with Heilmann to reach the present invention. Even further, if Laurin and

Barney are combined with Heilmann, Applicants submit respectfully that the Office Action still fails in its burden of obviousness for lack of disclosure of films having no measurable yield. Accordingly, Applicants requests respectfully that the rejections to Claims 10-13, 15-17, and 34 under 35 U.S.C. § 103(a) be withdrawn.

### **III. Rejections Under 35 U.S.C. § 112, Second Paragraph**

At page 2-3, paragraphs 2-6, of the Office Action, Claims 1-34 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to point out particularly and claim distinctly the subject matter regarded as the invention. In paragraphs 2, 5, and 6, the Office Action alleges that Claims 1, 23, and 25 are unclear because “consisting of” language is used but the phrase 'up to' makes it unclear whether the composition percentages add up to 100%. Applicants traverse respectfully.

Without acquiescing in the propriety of the rejection, and solely to advance the prosecution of the present application, Applicants amend Claims 1 and 23-25 to delete the expressions “up to” and “additionally up to.” Accordingly, in light of the remaining “consisting of” language in the claims, it is clear that the composition percentages add up to 100%. Applicants submit respectfully that the metes and bounds of Claims 1 and 23-25 are now clear and unambiguous.

In paragraph 2, the Office Action alleges further that the phrase “wherein following hot steam sterilization at 121 degrees Celsius the film displays no measurable yield according to DIN EN ISO 527-1” renders Claim 1 indefinite as the term “DIN EN ISO 527-1” is a standard, which may change with time. Further, the Office Action alleges that the standard is also not defined in the claim, thus the term “yield” has allegedly not been defined. Applicants traverse respectfully.



Without acquiescing in the propriety of the rejection, and solely to advance the prosecution of the present application, Applicants amend Claim 1 to add the term "1996" following the standard, as supported at page 15, line 26 of the present specification as filed. Applicants submit respectfully that, while international standards such as DIN ISO standards may change over time, one skilled in the art would easily be able to determine the standard in use in the year 1996, which does not change. Furthermore, Applicants submit respectfully that, as the Examiner is no doubt well aware, terms used in claims need not be defined in the claims, themselves; the specification is always available to interpret the claims. Hence, Applicants submit respectfully that the Office Action is in error in alleging that Claim 1 is indefinite for failing to provide a definition of certain terms within the claim. Respectfully, Applicants draw Examiner's attention to page 15, lines 21-26, wherein the definition of the term "yield" is provided. Accordingly, Applicants submit respectfully that the metes and bounds of Claims 1 are now clear and unambiguous.

Even further, the Office Action alleges in paragraph 2 that the term "hot" in Claim 1 is a relative term which renders the claim indefinite, and that the term "hot" is not defined by the claim and the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Applicants traverse respectfully.

Applicants submit respectfully that the term "hot" is part of the name of a technique known by those skilled in the art as "hot steam sterilization." Therefore, in this instance the use of the word "hot" is not a relative term which might render the claim indefinite. Furthermore, the complete recitation of the relevant portion of Claim 1 is "hot steam sterilization at 121°C or higher." Hence, one of ordinary skill in the art is indeed apprised of the requisite degree of heat.

In paragraph 3, the Office action alleges that Claim 14 is rendered indefinite by the phrase “the middle layer has a measurable yield” as the measurement, and therefore the term “yield,” have not been defined. The Office Action alleges further that the phrase “when measured separately” is indefinite as its meaning is unclear. Applicants traverse respectfully.

Without acquiescing in the propriety of the rejection, and solely to advance the prosecution of the present application, Applicants amend Claim 14 to recite “has a measurable yield of less than or equal to 8 Mpa when measured separately according to DIN EN ISO 527-1 to -3 1996.” As noted above, Applicants submit respectfully that the recitation of the standard and year of promulgation of the standard render the measurement and the term “yield” definite and clear. With regard to the phrase “when measured separately,” Applicants respectfully direct the Examiner’s attention to page 18, last paragraph, which describes desirable properties for an individual middle (M) layer of a multi-layer film of the present invention. In light of the specification, it is clear that the expression “when measured separately” means when the middle layer is measured for traction-elongation characteristics as a separate entity, apart from any other layers or materials of the multi-layer film of the claimed invention. Accordingly, Applicants submit respectfully that Claim 14 is clear and definite in its meaning.

In paragraph 4 of the Office Action, Claims 10-17 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite because the terms ‘Mpa’ and ‘Mpa’ are abbreviations that have not been defined. For purposes of examination, the abbreviations will be assumed to mean ‘megapascals’. Applicants traverse respectfully.

Without acquiescing in the propriety of the rejection, and solely to advance the prosecution of the present application, Applicants amend Claim 10 to provide the definition “megapascals (MPa)” as suggested by Examiner. Accordingly, Applicants submit

respectfully that Claim 10 and succeeding claims containing the term "MPa" are clear and definite.

In view of the above, Applicants suggests respectfully that the rejections have been overcome, and Applicants requests respectfully that the 35 U.S.C. § 112, second paragraph, rejection of Claims 1-34 be withdrawn.

### **CONCLUSION**


Applicants submit that the application is in condition for allowance. Favorable reconsideration, withdrawal of the rejections set forth in the above-noted Office Action, and an early Notice of Allowance are requested.

Applicants' undersigned attorney may be reached in our Washington, D.C. office by telephone at (202) 625-3500. All correspondence should be directed to our address given below.

### **AUTHORIZATION**

Applicants believe there is no additional fee due in connection with this filing. However, to the extent required, the Commissioner is hereby authorized to charge any fees due in connection with this filing to Deposit Account 50-1710 or credit any overpayment to same.

Respectfully submitted,

  
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